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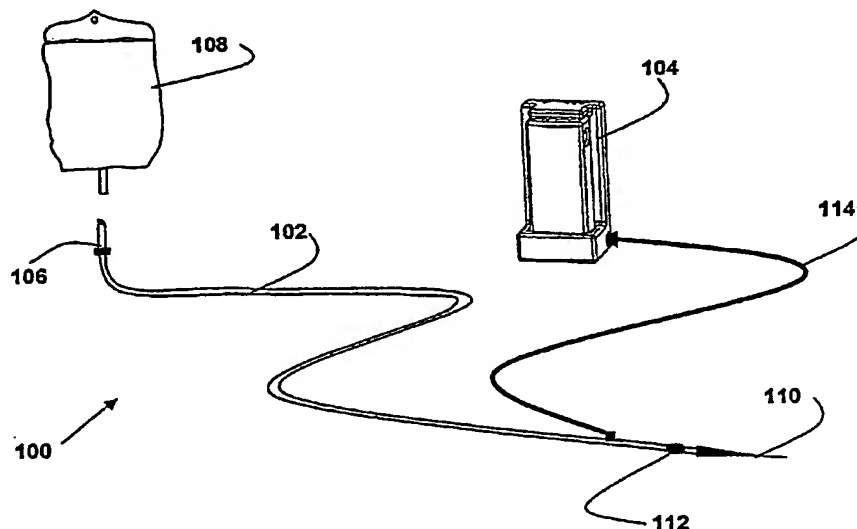
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Published:
— with international search report

[Continued on next page]

(54) Title: **METHOD AND SYSTEM FOR WARMING A FLUID**



(57) Abstract: The invention is directed generally to a method and system for controlling the temperature of a fluid, *i.e.*, warming or cooling a fluid, and more particularly, to a method and system for warming a fluid to be delivered to the body of a patient. In a preferred embodiment, a method and system for warming a fluid to be delivered into the body of a patient is provided and may include a controller and a fluid delivery-line. The fluid delivery-line may include an insulative tube and a fluid delivery tube positioned within the first tube and for communicating a fluid from a source to a destination. The fluid delivery-line may also include at least one thermal sensor positioned proximate the fluid delivery tube, a heating element positioned proximate the fluid delivery tube and a thermal medium positioned between the first tube and the second tube.

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— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(88) **Date of publication of the international search report:**
2 February 2006

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/13714

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61F 7/12

US CL : 604/113

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/113, 114, 207, 236

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6,746,439 B2 (LENKER) 8 June 2004 (8.06.2004), columns 3, 4, 8.	1-9, 11-13, 16-19, 22-27, 30, 31
Y	US 6,175,688 B1 (CASSIDY et al) 16 January 2001 (16.01.2001), column 12, lines 24-43; column 13.	20, 21, 28, 29
Y	US 6,488,659 B1 (ROSENMAN) 3 December 2002 (3.12.2002), column 2, lines 28-32.	10
Y	US 5,195,976 (SWENSON) 23 March 1993 (23.03.1993), column 5, lines 28-32.	14, 15

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

26 October 2005 (26.10.2005)

Date of mailing of the international search report

29 NOV 2005

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US

Commissioner for Patents

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MONICA A. GRAVES

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 64966-010150	FOR FURTHER ACTION	See item 4 below
International application No. PCT/US2004/013714	International filing date (<i>day/month/year</i>) 03 May 2004 (03.05.2004)	Priority date (<i>day/month/year</i>) 01 May 2003 (01.05.2003)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant THERMICS, LLC		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).
2. This REPORT consists of a total of 5 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

<input checked="" type="checkbox"/> Box No. I	Basis of the report
<input type="checkbox"/> Box No. II	Priority
<input type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/> Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/> Box No. VI	Certain documents cited
<input checked="" type="checkbox"/> Box No. VII	Certain defects in the international application
<input type="checkbox"/> Box No. VIII	Certain observations on the international application
4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 740 14 35	Date of issuance of this report 19 December 2005 (19.12.2005) Authorized officer <div style="text-align: center; font-weight: bold; font-size: 1.2em;">Athina Nickitas-Etienne</div> Telephone No. +41 22 338 89 95
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PATENT COOPERATION TREATY

REC'D 01 DEC 2005

From the
INTERNATIONAL SEARCHING AUTHORITY

WIPO PCT

PCT

To:
MICHEL MORENCY
GREENBERG TRAURIG, LLP
ONE INTERNATIONAL PLACE
BOSTON, MA 02110

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year) **29 NOV 2005**

FOR FURTHER ACTION
See paragraph 2 below

Applicant's or agent's file reference

64966-010150

International application No.

International filing date (day/month/year)

Priority date (day/month/year)

PCT/US04/13714

03 May 2004 (03.05.2004)

01 May 2003 (01.05.2003)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): A61F 7/12 and US Cl.: 604/113

Applicant

THERMICS, LLC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Date of completion of this
opinion
15 November 2005 (15.11.2005)

Authorized officer

Kevin J. Simons

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MONICA A. GRAVES

Facsimile No. (571) 273-3201

Form PCT/ISA/237 (cover sheet) (April 2005)

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US04/13714

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in electronic form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US04/13714

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>10, 14, 15, 20, 21, 28, 29</u>	YES
	Claims <u>1-9, 11-13, 16-19, 22-27, 30 and 31</u>	NO
Inventive step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-31</u>	NO
Industrial applicability (IA)	Claims <u>1-31</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-9, 11-13, 16-19, 22-27, 30 and 31 lack novelty under PCT Article 33(2) as being anticipated by Lenker (US Patent No. 6,746,439). Lenker discloses a system and method for heating a fluid for delivery into the body, comprising a controller, a fluid delivery line with one end receiving a fluid and the other end delivering the fluid, an insulative tube, a fluid delivery tube within the first tube of the fluid delivery line, a thermal sensor and heating elements all proximate to the fluid delivery tube, and a thermal medium between the first and second tubes of the fluid delivery line.

Claims 10 lacks an inventive step under PCT Article 33(3) as being obvious over Lenker in view of Rosenman. US Patent No. 6,488,659 B1. Lenker discloses the invention substantially as claimed except for a thermal medium being comprised of a fluid. Rosenman discloses a fluid, such as a gas or liquid surrounding the fluid delivery tube in order to help keep the solution in the fluid delivery tube in its desired state.

Claims 14 and 15 lack an inventive step under PCT Article 33(3) as being obvious over Lenker in view of Swenson. US Patent No. 5,195,976. Lenker discloses the invention substantially as claimed except for the controller being connected to a power source, consisting of either a battery, AC or DC power. Swenson, however, discloses that the controller can be powered by either AC or DC current, and can also be powered by a battery.

Claims 20, 21, 28 and 29 lack an inventive step under PCT Article 33(3) as being obvious over Lenker in view of Cassidy et al. US Patent No. 6,175,688 B1. Lenker discloses the invention substantially as claimed except for the system including a temperature actuated valve and method of activating the valve. Cassidy et al., however, disclose a valve system and method of operation, operated by shape memory wires, which start and stop the flow of fluid within the fluid delivery tube upon the temperature of the fluid within the fluid delivery tube, and hence the shape memory wires, reaching a predetermined value.

Claims 1-31 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US04/13714

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

The subject matter of this application admits of illustration by drawing to facilitate understanding of the invention. Page 10 of Applicant's specification mentions a Figure 2B, however Fig. 2B is not included as one of the drawings. Applicant is required under PCT Article 7(1) to furnish a drawing.

The drawings are objected to under PCT Rule 66.2(a)(iii) as containing the following defect(s) in the form or content thereof: element 1004 is found in Fig. 9c, but is not described within the specification. Additionally elements 1902 and 1903, found in Fig. 19, as well as element 2302, found within Fig. 23c are not described within the specification.

The description is objected to as containing the following defect(s) under PCT Rule 66.2(a)(iii) in the form or contents thereof: Page 11 of the specification has a grammatical error in the first paragraph, in the sentence "In one embodiment if the invention the tubing has an ID at least about 0.05" in which the word "if" should be changed to "of". Also on page 11, the phrase within the last sentence "insertion thermal" should read "insertion of thermal." The phrase "to set them temperature" on page 15, first paragraph, first sentence should be changed to "to set the temperature." The word "types" within the first sentence of the fifth paragraph on page 16 should be changed to "type." The word "bold" within the third to last sentence of the paragraph [00101] on page 18 should be changed to "bolt." The phrase "such that they connected" within the sixth sentence of the paragraph labeled [00107] on page 20 should be changed to "such that they can be connected." The word "contact" within the third sentence of paragraph labeled [00110] on page 21 should be changed to "contacts." The phrase "such that they connected" in the third sentence of paragraph [00111] on page 21 should be changed to "such that they are connected." Numbers 2102 and 2103 within paragraph [00116] on page 23 should be bolded to comply with the precedence set forth with the bolding of the other elements within the drawings. The phrase "FIG. 2A" within the second sentence of paragraph [00120] on page 24 should be changed to "FIG. 22A." The phrase "exposed on one of the silicone plug" in the second sentence of paragraph [00126] on page 25 should be changed to "exposed on one end of the silicone plug." Also within that paragraph, the last sentence should be changed to "This design is well-suited ..." The phrase "exposed on one of the push-pin" in the third sentence of paragraph [00127] on page 26 should be changed to "exposed on one end of the push-pin."

Claims 10, 13, 14, 15 and 17 are objected to under PCT Rule 66.2(a)(iii) as containing the following defect(s) in the form or contents thereof: Claim 10 appears to depend from claim 9, not directly from claim 1, as the antecedent phrase "thermal medium" is actually found in claim 9. Likewise, claims 13 and 14 depend from claim 2, not claim 1, because the antecedent phrase "the controller" is found in claim 2. Additionally claim 15 depends from claim 14, not claim 2, because the antecedent phrase "power source" is found within claim 14.